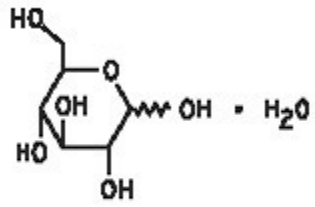
DEXTROSE - dextrose injection
BAXTER HEALTHCARE CORPORATION

DESCRIPTION

5% Dextrose Injection, USP in the MINI-BAG Plus Container is a sterile, nonpyrogenic solution for intravenous administration after admixture with a single dose powdered drug. It contains no antimicrobial agents. Each 100 mL contains 5 g of Dextrose Hydrous, USP. The osmolarity is 252 m0smol/L (calculated). The pH is 4.0 (3.2 to 6.5). The chemical structure for Dextrose Hydrous, USP is shown below.



D-Glucose monohydrate

The MINI-BAG Plus Container is a standard diluent container with an integral drug vial adaptor. It allows for drug admixture after connection to a **single dose** powdered drug vial having a **20 mm closure.** A breakaway seal in the tube between the vial adaptor and the container is broken to allow transfer of the diluent into the vial and reconstitution of the drug. The reconstituted drug is then transferred from the vial into the container diluent and mixed to result in an admixture for delivery to the patient.
The VIAFLEX plastic container is fabricated from polyvinyl chloride (PL 146 Plastic). Exposure to temperatures above 25° C/77° F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period. The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

5% Dextrose Injection, USP has value as a source of water and calories. It has a caloric content of approximately 170 kcal/L. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE

5% Dextrose Injection, USP is indicated as a source of water and calories and may also be used as diluent for reconstitution of a powdered drug product packaged in a vial with a 20 mm closure.

CONTRAINDICATIONS

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

WARNINGS

Dextrose injections should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or hemolysis.
The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutive states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections.
Excessive administration of dextrose injections may result in significant hypokalemia.
For use only with a single dose powdered drug vial with a 20 mm closure.
Do not administer unless drug is completely dissolved and drug vial is empty.
Additives may be incompatible.
Do not remove drug vial at any time prior to or during administration.
In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage.

GENERAL PRECAUTIONS

General
Do not administer unless solution is clear and all seals are intact. Dextrose injections should be used with caution in patients with overt or subclinical diabetes mellitus.

Laboratory Tests
Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Carcinogenesis and Mutagenesis and Impairment of Fertility
Studies with 5% Dextrose Injection, USP have not been performed to evaluate the carcinogenic potential, mutagenic potential or effects on fertility.

Pregnancy

Pregnancy Category C
Animal reproduction studies have not been conducted with 5% Dextrose Injection, USP. It is also not known whether Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose Injection, USP should be given to a pregnant woman only if clearly needed.

Nursing Mothers
Caution should be exercised when 5% Dextrose Injection, USP is administered to a nursing woman.

Pediatric Use
Dextrose is safe and effective for the stated indications in pediatric patients (see INDICATIONS AND USAGE). As reported in the literature, the dosage selection and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

ADVERSE REACTIONS
Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION
As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.
All injections in MINI-BAG Plus Containers are intended for intravenous administration using sterile equipment.
Do not remove unit from overwrap until ready for use. The overwrap is a moisture barrier.

To Open
Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity should diminish gradually.
Prior to use, check that the vial adaptor cover is intact. Check the solution container for minute leaks by squeezing inner bag firmly. If leaks are found or if the vial adaptor cover is not intact, discard product as sterility may be impaired.

To Assemble and Reconstitute
See other side for detailed instructions.
Additives may be incompatible.

HOW SUPPLIED
5% Dextrose Injection, USP in MINI-BAG Plus Container is available as follows:

Code	Size (mL)	NDC
2B0040	50 mL	NDC 0338-0551-11

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C/77° F).

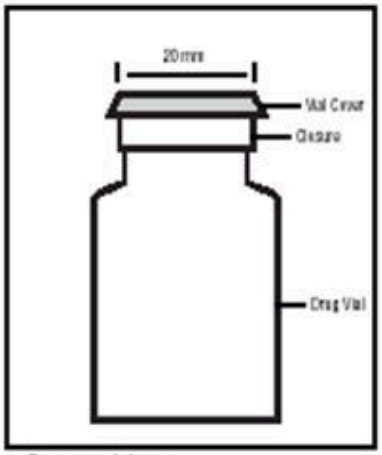
MINI-BAG PLUS CONTAINER DIRECTIONS

ONLY FOR SINGLE DOSE POWDERED DRUG VIALS WITH 20 MM CLOSURES

USE ASEPTIC TECHNIQUE

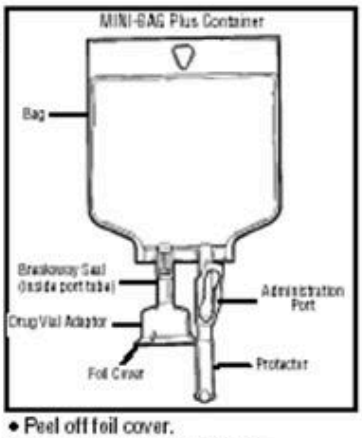
Assembly

1



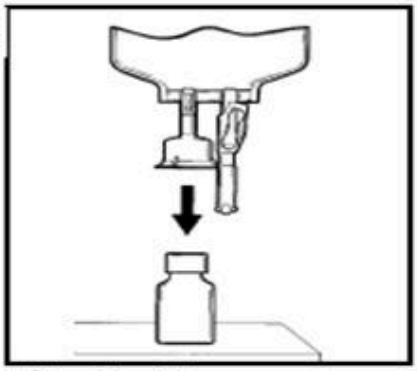
- Remove vial cover.
- Disinfect stopper.

2



- Peel off foil cover.
- Inspect adaptor for moisture. Discard if found.

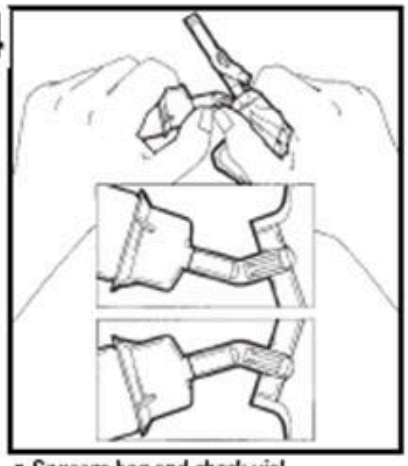
3



- Place vial upright.
- Hold firmly.
- Push adaptor down until vial snaps in place.
- DO NOT TWIST.
- Pull vial to ensure fully seated.

Reconstitution

4



- Squeeze bag and check vial.
- Use only if vial fully seated and dry.
- Bend up then down to break seal.

5

- Hold bag with vial down.
- Squeeze solution into vial until **half full.**
- Shake to suspend drug in solution.

6

- Hold bag with vial upside down.
- Squeeze bag to force air into vial.
- Release to drain suspended drug from vial.
- Repeat steps 5 and 6 until vial is **empty** of drug and solution is thoroughly mixed. **Ensure drug is completely dissolved. Do Not Remove Drug Vial.**

7. Remove port protector. Attach administration set per its directions.

8. Hang container on I.V. pole and prime set per directions. Ensure that vial is empty of drug and solution. Repeat step 6 if drug and solution remain in vial.

Warning: Do not use in series connections.

9. Administer medication per directions. Use within specified time for drug stability. Refer to drug package insert.

Baxter Healthcare Corporation

Deerfield, IL 60015 USA

Printed in USA

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PACKAGE LABEL.PRINCIPLE DISPLAY PANEL

5% Dextrose Injection, USP Container Label

LOT EXP
5% Dextrose
Injection USP
MINI-BAG Plus Container
50mL

2B0040
NDC 0338-0551-11
EACH 50 mL CONTAINS 2.5 g DEXTROSE HYDROUS USP
pH 4.0 (3.2 TO 6.5) OSMOLARITY 252 mOsmol/L
(CALC) STERILE NONPYROGENIC READ PACKAGE INSERT FOR FULL
INFORMATION ADDITIVES MAY BE INCOMPATIBLE DOSAGE
INTRAVENOUSLY AS DIRECTED BY A PHYSICIAN CAUTIONS MUST NOT BE
USED IN SERIES CONNECTIONS DO NOT ADMINISTER SIMULTANEOUSLY
WITH BLOOD DO NOT USE UNLESS SOLUTION IS CLEAR **RX ONLY**
US PAT NOS 4 340 049 4 607 671 5 304 163
BAXTER HEALTHCARE CORPORATION
DEERFIELD IL 60015 USA
MADE IN USA
VIAFLEX SINGLE DOSE CONTAINER
PL 146 PLASTIC
BAXTER VIAFLEX MINI-BAG
AND PL 146 ARE TRADEMARKS OF
BAXTER INTERNATIONAL INC
BREAK SEAL AND MIX BEFORE USE

Lot: PXX
QTY: 80-50 mL

Exp: XX XX
Code: 2B0040

NDC: 0338-0551-11

5% DEXTROSE INJECTION, USP
IN MINI-BAG PLUS CONTAINER

(17) XXXX00 (10) PXX

(01) 50303380551113

01/09/09 16:20:36

5% Dextrose Injection, USP Carton Label

Lot:PXX Exp:XX XX
QTY:80-50mL
Code: 2B0040
NDC: 0338-0551-11
5% DEXTROSE INJECTION, USP
IN MINI-BAG PLUS CONTAINER

(17) XXXX00 (10) PXX
(01) 50303380551113